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EXAMINER	
DELLA, JAYMI E	
ART UNIT	PAPER NUMBER
3739	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,631	HILLELY, RON	
	Examiner	Art Unit	
	JAYMI DELLA	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-32 and 34-70* is/are rejected.

7)☒ Claim(s) *10 and 33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 September 2009* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The following is a Final Office Action in response to communications received 9/10/2009. Claims 1, 31, 37, and 68 have been amended. Thus, claims 1-70 are pending and addressed below.

Response to Amendment

2. Applicant's amendments to the specification are sufficient to overcome the specification objections set forth in the previous office action.

3. The drawings were received on 9/10/2009. The drawing for Fig. 11 now shows "cryoprobes 290". The drawing for Fig. 9 now shows parts of the "circular markings". It is noted that these were not visible in the drawings received 10/19/2005. However, the drawings are still objected as discussed below.

4. Applicant's amendments to claims 31 and 68 are sufficient to overcome the 35 USC 112, 2nd paragraph rejections set forth in the previous office action.

5. Applicant's amendments to the claim 37 and 68 are sufficient to overcome the 35 USC 101 rejections set forth in the previous office action.

Drawings

6. The drawings are objected to because the photographs for Fig. 7 and 9-11 have poor line quality as far as showing all the details of the claim invention, especially Fig. 11.

Black and white photographs, including photocopies of photographs, are not ordinarily

permitted in utility and design patent applications. The Office will accept photographs in utility and design patent applications, however, if photographs are the only practicable medium for illustrating the claimed invention. For example, photographs or photomicrographs of: electrophoresis gels, blots (e.g., immunological, western, Southern, and northern), auto- radiographs, cell cultures (stained and unstained), histological tissue cross sections (stained and unstained), animals, plants, in vivo imaging, thin layer chromatography plates, crystalline structures, and, in a design patent application, ornamental effects, are acceptable. If the subject matter of the application admits of illustration by a drawing, the examiner may require a drawing in place of the photograph. The photographs must be of sufficient quality so that all details in the photographs are reproducible in the printed patent. (MPEP 608.01(f))

7. It is suggested that Applicant submit non-photograph drawings, since it is the Examiner's opinion that photographs are not the only predictable medium for illustrating the claimed invention, and they would more clearly show the elements of the claimed invention.

8. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate

changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

9. Claim 33 is objected to because of the following informalities: replaced "Te" with --The--. Appropriate correction is required.

10. Claim 33 is objected to because of the following informalities: replaced "insertable" with --inserted--. Appropriate correction is required.

11. Claim 38 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 38 recites "…further comprising said orientation probe", but the orientation probe is already recited in claim 37. This objection relates to the 35 USC 112, second paragraph rejection made below. Appropriate correction is required.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 37-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 37 recites: "A device for guiding a therapeutic probe to a treatment target, comprising: an orientation probe…". It is unclear whether applicant is claiming the subcombination of the "device for guiding" or the combination of the device and orientation probe (and in a dependent claim, the therapeutic probe). It is suggested that applicant replace the preamble with: --A system for guiding a therapeutic probe to a treatment target...-- to properly claim the combination. For purposes of examination, the combination will be searched and examined.

14. Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 40 recites: "…wherein said therapeutic probe is a cryoprobe." It is unclear whether this is the therapeutic probe referred to in claim 37 or the therapeutic probe referred to in claim 39. For purposes of examination, it will be the first therapeutic probe referred to in claim 37.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claims 1-6, 11-12, 16-23, 26, 32, 34, 37-38, 42-44, 49-50, 53-60, 63, and 69 are rejected under 35 U.S.C. 102(e) as being anticipated by Schatzberger (WO 2004/002319).

17. Concerning **claim 1**, Schatzberger discloses **a method for guiding a therapeutic probe to a treatment target within the body of a patient** (method for delivering a surgical instrument to a treatment site within the body of a subject; Abstract)**, comprising:**

(a) inserting an orientation probe into the body of a patient and positioning said orientation probe so that said orientation probe has a known spatial relationship to said treatment target (catheter orientation probe 250 with guiding elements 130, 132 is inserted into the body of the patient to reference site 125 which has a known spatial relationship to the treatment site using imaging modalities and patient specific physiology; Page 14, Lines 17-20, Page 15, Lines 15-19, Fig. 10)**, then subsequently**

rigidly affixing to said orientation probe a template which comprises at least one probe guide operable to constrain movement of a therapeutic probe

inserted therethrough in a controlled direction, said controlled direction being aligned with said treatment target when said template is rigidly affixed to said inserted orientation probe (orientation probe 250 is connected to template 230 at connecting joint 270 and the template is rotated around joint 270 to orient it perpendicular to guiding segment 132, at which time the connecting joint is locked in place, thus rigidly affixing the template 230 to the orientation probe 250. Template 230 is comprised of probe guide apertures 240 through which treatment tools 140 are inserted into the treatment site in determined directions in parallel and held perpendicular to template 230 once the template 230 is rigidly affixed to the catheter orientation probe 250; Page 18, Line 11-12; Page 23, Lines 14-20; Fig. Fig. 2b and 11)**;** **and**

(b) inserting at least one therapeutic probe through said at least one probe guide into the body of a patient, thereby guiding said inserted therapeutic probe to said treatment target (therapeutic treatment tool probes 140 are inserted into the probe guide apertures 240 and guided to the treatment site as shown by dotted directional lines 160; Page 18, Lines 10-14; Fig. 11).

18. Concerning **claim 2**, Schatzberger discloses the therapeutic probes (140) to be cryoprobes, and thus it is inherent that upon insertion, they are operated to cryoablate tissue at the treatment site (Column 12, Lines 15-19).

19. Concerning **claims 3-4**, as discussed in the rationale applied to claim 1, Schatzberger discloses using an ultrasound imaging modality to position the orientation probe (250) (Page 14, Lines 17-20 and Page 15, Lines 18-19).

20. Concerning **claim 5**, Schatzberger discloses the distal portion of the orientation probe to be positioned within the treatment target (Fig. 11).

21. **Claim 6** is rejected upon the same rationale as presented for claim 2.

22. Concerning **claim 11**, Schatzberger discloses the template (230) comprising a plurality of probe guide apertures (240) which constrain the therapeutic probes (140) to movement along a predetermined axis that is perpendicular to template (230) (Page 18, Lines 11-14; Fig. 7-8).

23. **Claim 12** is rejected upon the same rationale as presented for claim 1.

24. **Claims 16-21** are rejected upon the same rationale as presented for claim 11.

25. Concerning **claim 22**, Schatzberger discloses the common direction being parallel to the longitudinal axis of the guiding element (132) of the orientation probe (250) when the probe (250) is affixed to the template (230) via locked joint (27) (Fig. 11)

26. **Claim 23** is rejected upon the same rationale as presented for claim 11.

27. Concerning **claim 26**, Schatzberger discloses the probe guides (240) to be of fixed perpendicular orientation with respect to the template (230) (Page 18, Lines 11-14).

28. Concerning **claim 32**, for purposes of examination, clamp will be defined as: "to hold something firmly and tightly in position" (Encarta Online Dictionary). Schatzberger discloses rigidly affixing the template (230) to the orientation probe (250) by locking connecting joint (270) in place, thus locking connecting joint (270) with distal end (252) of the orientation probe (250), the two parts are clamped together because they are

held tightly in position and exert a pressure on one another. Thus, the template is rigidly affixed by pressure clamping.

29. Concerning **claim 34**, Schatzberger discloses at least a portion of the treatment target being within the prostate (200) (Fig. 2a).

30. Concerning **claims 37-38**, Schatzberger discloses **a device for guiding a therapeutic probe to a treatment target within the body of a patient** (device for delivering a surgical instrument to a treatment site within the body of a subject; Abstract)**, comprising:**

(a) an orientation probe capable of being insertable into the body of a patient in such a manner that a distal portion of said orientation probe is positioned within said treatment target (catheter orientation probe 250 with guiding segments 130, 132; Fig. 10)**; and**

(b) a template independent of said orientation probe but capable of being rigidly affixed to said orientation probe after said orientation probe is so inserted and positioned, said template comprises at least one probe guide operable to constrain movement of a therapeutic probe inserted therethrough in such a manner that if said orientation probe is so positioned and said template is so affixed, then said therapeutic probe inserted through said probe guide will be constrained to move towards said target (template 230 is independent of orientation probe 250 but can be rigidly affixed to probe 250 at connecting joint 270 after it is inserted and position in the patient. Template 230 is comprised of probe guide apertures 240 through which treatment tools 140 are inserted into the treatment site in

determined directions in parallel into the treatment site and held perpendicular to template 230 once the template 230 is rigidly affixed to the catheter orientation probe 250; Page 18, Line 11-12; Page 23, Lines 14-20; Fig. Fig. 2b and 11).

31. **Claim 42** is rejected upon the same rationale as presented for claim 37.

32. **Claims 43-44** is rejected upon the same rationale as presented for claim 2.

33. **Claim 49** is rejected upon the same rationale as presented for claim 11.

34. **Claim 50** is rejected upon the same rationale as presented for claim 12.

35. **Claims 53-58** are rejected upon the same rationale as presented for claim 11.

36. **Claim 59** is rejected upon the same rationale as presented for claim 22.

37. **Claim 60** is rejected upon the same rationale as presented for claim 11.

38. **Claim 63** is rejected upon the same rationale as presented for claim 26.

39. **Claim 69** is rejected upon the same rationale as presented for claim 32.

40. Claims 1, 9, 11, 24, 29, 37-39, 49, and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Scarbrough et al. (4,998,912).

41. Concerning **claims 1 and 11**, as illustrated in Fig. 4 and 6, Scarbrough et al. disclose **a method for guiding a therapeutic probe to a treatment target within the body of a patient** (method for guiding therapeutic needle probes to a target to treat cancer within the body of a patient; Column 1, Lines 5-10)**, comprising:**

(a) inserting an orientation probe into the body of a patient and positioning said orientation probe so that said orientation probe has a known spatial relationship to said treatment target (central tandem 40 is taken to be the orientation

probe and is intracavitally employed and positioned with a known relationship in the uterus after determining the uterus' size and shape; Column 5, Lines 20-25; Fig. 6)**, then subsequently**

rigidly affixing to said orientation probe a template which comprises at least one probe guide operable to constrain movement of a therapeutic probe inserted therethrough in a controlled direction, said controlled direction being aligned with said treatment target when said template is rigidly affixed to said inserted orientation probe (an obturator 38 is then affixed to the tandem 40 with an Allen screw 60 and then halves 20 and 22 of the template block are bolted together and template 18 is fitted over the distal end 76 of the obturator and is positioned against the perineum. The template 18 is affixed to the obturator 38 by means of Allen screws 54. The template 18 has probe guides 24', 26', 28', and 30' through which needles 24-30 are inserted in a controlled direction that is aligned with the treatment target, within the uterus, after the template is affixed to the obturator which is affixed to the central tandem, taken to be the orientation probe. Thus, the template is also affixed to the central tandem; Column 5, Lines 30-52)**; and**

(b) inserting at least one therapeutic probe through said at least one probe guide into the body of a patient, thereby guiding said inserted therapeutic probe to said treatment target (needles 24-30 are inserted to give radioactive doses to the cancer target; Column 5, Lines 46-48).

42. Concerning **claim 9**, Scarbrough et al. disclose the central tandem (40) and obturator (38) being rigidly affixed to the template by an elastic pressure clamp when

they are respectively affixed using Allen screws (54, 60) (Column 4, Lines 40-43 and Column 5, Lines41-42).

43. Concerning **claim 24**, Scarbrough et al. disclose the central tandem (40) as the orientation probe as discussed in claim 1 above, and also that central tandem (40) gives a radioactive dosage to the interior of the uterus, and is thus also a therapeutic probe (Column 5, Lines 21-23).

44. Concerning **claim 29**, Scarbrough et al. disclose the probe guides (24'-28') having axes oriented to disperse distal portions of the probes (24-38) (Fig. 4).

45. Concerning **claims 37-38 and 49**, Scarbrough et al. disclose **a device for guiding a therapeutic probe to a treatment target within the body of a patient** (device for guiding therapeutic needle probes to a target to treat cancer within the body of a patient; Column 1, Lines 5-10)**, comprising:**

(a) an orientation probe capable of being insertable into the body of a patient in such a manner that a distal portion of said orientation probe is positioned within said treatment target (central tandem 40 is taken to be the orientation probe and is intracavitally employed and positioned with a known relationship in the uterus after determining the uterus' size and shape; Column 5, Lines 20-25, Fig. 6)**; and**

(b) a template independent of said orientation probe but capable of being rigidly affixed to said orientation probe after said orientation probe is so inserted and positioned, said template comprises at least one probe guide operable to constrain movement of a therapeutic probe inserted therethrough in such a

manner that if said orientation probe is so positioned and said template is so affixed, then said therapeutic probe inserted through said probe guide will be constrained to move towards said target (template 18 is rigidly affixed to the orientation probe 250 via obturator 38 with Allen screws 54 and 60 after the orientation probe is inserted and positioned within the uterus. Template 18 has probe guides 24'-30' that constrain movement of therapeutic probes 24-30 towards the treatment target when they are inserted through the probe guides; Column 5, Lines 30-52; Fig. 6).

46. **Claim 39** is rejected upon the same rationale as applied to claim 24.

47. **Claim 66** is rejected upon the same rationale as applied to claim 29.

Claim Rejections - 35 USC § 103

48. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

49. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

50. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

51. Claims 7-8 and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schatzberger (WO 2004/002319), as applied to claims 6 and 42, and in further view of Zvuloni (6,706,037, previously cited).

52. Concerning **claims 7-8 and 45-46**, Schatzberger fails to disclose cryoprobes operable by Joule-Thomson cooling or heating. However, Zvuloni discloses a cryosurgical apparatus using Joule-Thomson heat exchanges with passageway (10) that includes a plurality of orifices for passage of high-pressure gas so as to cool or heat selective portions of the device. (Column 12, Lines 42-48). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use Joule-Thomson cooling and heating cryoprobes in order to provide the benefit of having two-stage cooling with Joule-Thomson heat exchangers which presents the advantages of more rapid and more efficient cooling as taught by Zvuloni (Column 3, Lines 1-6).

53. **Claims 13-15, 31, 51-52, and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schatzberger (WO 2004/002319), as applied to claims 1 and 37, in view of Schatzberger (6,142,991, previously cited).**

54. Concerning **claims 13-14 and 51-52**, Schatzberger '319 fails to disclose an orientation or therapeutic probe with a set of marks useable to measure a distance of insertion. However, Schatzberger '991 discloses a cryosurgical method and apparatus that uses probes with a scale for indicating depth of penetration into the target tissue (Column 11, Lines 53-54). At the time of the invention, it would have been obvious to one of ordinary skill in the art to use a set of marks on each of the probes in order to provide the benefit of indicating the depth of penetration into the target tissue as taught by Schatzberger.

55. Concerning **claim 15**, Schatzberger '319 discloses inserting therapeutic probes (140) so that the active treatment heads (142) extend in length approximately the distance between guiding segment proximal point (134) and guiding segment distal point (136), and if treatment tools (140) are extended through template (230) to a distance such that the proximal limit of their active treatment heads (142) extends beyond template (130/230) at a distance equal to the distance "L", a predetermined ablation volume will result. Thus, the therapeutic probes (140) are inserted to a distance with a selected relationship to a measured distance of the orientation probe (250) to create the ablation volume that surrounds guiding element (132) of orientation probe (250). (Pages 19-20, Lines 28-6; Fig. 7-8)

56. Concerning **claims 31 and 68**, Schatzberger '319 fails to teach that the template comprises circular markings indicating boundaries of tissue destruction expected when ablation probes are inserted through the probe guides and the ablation probes are activated to ablate the body tissue. Schatzberger '991 discloses a method and apparatus that applies an imaging device such as ultrasound, MRI or CT to form a three-dimensional grid of the treatment target (Column 10, Lines 59-63). Schatzberger '991 discloses a template (115) with probe guide apertures (120), each aperture serving for insertion of a cryosurgical probe. (Column 11, Lines 1-5) A net of marks (112) is provided on image (114) being accurately correlated to the net of apertures (120) on guiding element (115). Marks (112) on image (114) sign the exact locations of the ice-ball centers formed at the end of cryosurgical probes inserted through apertures (120). Sets of image (114) taken at various depths provides a three-dimensional grid of the treatment target and is used for planning the cryosurgical procedure. (Column 11, Lines 10-30; Fig. 5 and 9) A plurality of cryoprobes are inserted through apertures (120) of template (115) into the treatment target. Each probe is inserted to a specific depth, providing local effective treatment to distinct segments of the treatment target while avoiding damaging other tissue segments. (Column 11, Lines 46-52) At the time of the invention, it would have been obvious to one of ordinary skill in the art to use the circular markings on the images in order to indicate the centers of the ice-ball formations, and thus, knowing the radius, compute the ablation volume, in order to provide the benefit of knowing what tissue will be ablated by the cryoprobes. Further, at the time of the invention, it would have been obvious to one of ordinary skill in the art to place these

markings on the template itself in order to provide the benefit of the surgeon not having to take his field of view off template.

57. **Claims 24-25, 39-40, and 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scarbrough et al. (4,998,912), as applied to claims 1 and 37-38, in view of Downey (6,206,832, previously cited).**

58. Concerning **claims 24-25, 39-40, and 61-62**, Scarbrough et al. fail to disclose the orientation probe being a therapuetic cryoprobe. However, Downey et al. discloses a method for facilitating the placement of medical instruments into a target tissue using a template (15) that has a plurality of regularly spaced apertures (30) sized to allow at least one medical instrument (i.e., biopsy needle, cryosurgical probes, etc.) to pass through reference plate (15) (Column 5, Lines 23-25, 34-40 and Column 7, Lines 55-64). Thus, any type of probe that is used for percutaneous treatment of body tissues can be used. An optimal trajectory of insertion to the treatment target area via apertures (30) in reference plate (15) is determined and the medical instrument is inserted. Upon insertion of the medical instrument (i.e., cryoprobe), its actual trajectory is monitored with ultrasonographic imaging, and thus is also an orientation probe with respect to the treatment target area. (Column 6, Lines 39-58, Column 7, Lines 8-11) At the time of the invention, it would have been obvious to one of ordinary skill in the art to use therapeutic cryoprobes and a therapeutic orientation cryoprobe in order to provide the benefit of a functionally equivalent method of destroying tissue using the minimally invasive cryosurgical techniques as taught by Downey (Column 1, Lines 29-40), and

inserting one less therapeutic cryoprobe into the treatment target area, thus shortening the time needed for the procedure.

59. **Claims 27-29 and 64-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schatzberger (WO 2004/002319), as applied to claims 11 and 37, in view of Downey (6,206,832, previously cited).**

60. Concerning **claims 27-29 and 64-66**, Schatzberger fails to disclose at least one probe guide that is of variable orientation with respect to the template. However, Downey discloses a template (15) with a plurality of probe guide apertures (30) through which therapeutic cryosurgical probes are inserted (Column 5, Lines 34-40, Column 7, Lines 55-64). Apertures (30) are provided with an internal adjustment means (50), which comprises a ball (55) disposed within complementary socket (60). Each ball (55) has a passageway (65) sized to receive a portion of therapeutic probe (40) that forms part of aperture (30) and is rotatable around axle (70). (Column 6, Lines 8-20) Internal adjustment means (50) provides the practitioner with the ability to make minor adjustments to the trajectory of the instrument during placement and within the target tissue (Column 7, Lines 16-23). Because each aperture has an individual internal adjustment means, each aperture can be made to have a commonly oriented axes direction. Each aperture axis will be parallel to the longitudinal probe axis fixed within ball (55); therefore, when ball (55) rotates around axle (70), both the aperture axis and probe axis rotate in parallel. The internal adjustment means provides approximately thirty to fifty degrees range of movement for the probe placed through the aperture (30)

from an axis perpendicular to the reference means' face plane allowing each probe guide (30) to have a variable orientation with respect to the template (15) and for the user to either concentrate or disperse the distal ends of the probes (Column 6, Lines 31-38). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have probe guides with variable orientations to be able to disperse or concentrate the distal ends of the therapeutic probes in order to provide the benefit of allowing minor adjustment to the selected treatment target path as taught by Downey et al. (Abstract)

61. **Claims 30 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schatzberger (WO 2004/002319), as applied to claims 1 and 37, in view of Whitmore, III et al. (5,931,786, previously cited).**

62. Concerning **claims 30 and 67**, Schatzberger fails to disclose a template made of ertacetal resin. Whitmore, III et al. discloses that all the components of a template grid support apparatus for medical instruments can be fabricated or cast of a plastic, with engineering thermoplastics, such as DELRIN® (Column 4, Lines 10-16). Because both Schatzberger and Whitmore, III et al. teach the use of a template to guide medical instruments to a selected treatment target, it would have been obvious to one of ordinary skill in the art at the time of the invention to make the template of ertacetal resin, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of

obvious design choice. *In re Leshin*, 125 USPQ 416. See also *Ballas Liquidating Co. v. Allied industries of Kansas, Inc.* (DC Kans) 205 USPQ 331.

63. Claims 35-36, are rejected under 35 U.S.C. 103(a) as being unpatentable over Schatzberger (WO 2004/002319) as applied to claim 1, in view of Morra et al. (*Choices,* previously cited).

64. Concerning claims 35-36, Schatzberger fails to disclose that a portion of the treatment target is within the liver or the kidney. At the time of the invention, it would have been obvious to one of ordinary skill in the art to adapt Downey et al.'s minimally invasive percutaneous cryosurgical technique for use on with different treatment targets, such as the liver or kidney, because it is a common practice in the art to use cryosurgery for treatment of cancer of the prostate, liver, and kidney as exemplified in the teachings of Morra et al (Page 181) in order to gain the benefits of ablating unwanted tissue at the target site.

65. Claims 37, 41, 47-48, and 69-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zurinski et al. (4,542,747, previously cited).

66. Concerning **claims 37 and 41**, **a device for guiding a therapeutic probe to a treatment target within the body of a patient** (ultrasonic applicator 2 is capable of guiding a therapeutic biopsy probe to a treatment target within the body of a patient; Column 6, Lines 39-42)**, comprising:**

(a) an orientation probe capable of being insertable into the body of a patient in such a manner that a distal portion of said orientation probe is positioned within said treatment target (biopsy needle 37 is taken to be an orientation probe, is clearly visible via ultrasound because it is made of metal, so it produces an easily distinguishable ultrasonic contrast with the surrounding biological tissue, and is capable of having its distal end inserted into the body of a patient and positioned at the treatment target site; Column 1, Lines 47-51Fig. 3)**; and**

(b) a template independent of said orientation probe but capable of being rigidly affixed to said orientation probe after said orientation probe is so inserted and positioned, said template comprises at least one probe guide operable to constrain movement of a therapeutic probe inserted therethrough in such a manner that if said orientation probe is so positioned and said template is so affixed, then said therapeutic probe inserted through said probe guide will be constrained to move towards said target (first and second partial bodies 4, 6 are arranged parallel to one another with probe guide channels 50, 52, 54, and form a template to snugly receive a biopsy needle. The template is capable of rigidly affixing to an orientation probe after the orientation probe is inserted and positioned in the body by operating hand grips 64, 66 to open and close partial bodies 4, 6 around the probe. ; Column 6, Lines 11-15, Column 7, Lines 16-24 and Column 8, Lines 14-17 and 26-43; Fig. 8 and 10)**.**

Zurinski et al. fail to disclose a therapeutic probe that is inserted through a different probe guide channels, that when inserted, are constrained to move towards the

treatment target. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a second therapeutic biopsy probe in order to provide the benefit of taking biopsy samples in two different areas of the treatment target thereby saving time and discomfort to the patient by obviating the need to take two samples at two different times or two different procedures, and since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co., 193 USPQ 8*. Further, it would have been an obvious matter of design choice to size the probe guide channels not being used by the orientation probe or use smaller diameter therapeutic biopsy probes such that when a therapeutic probe is inserted, it can move through the guide channel and be constrained to move towards the treatment target, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955). Further, at the time of the invention, it would have been obvious to use variable diameter therapeutic biopsy needle probes in order to provide the benefit of taking differently sized biopsy samples.

67. Concerning **claims 47-48 and 69**, Zurinski et al disclose the template comprising an elastic pressure clamp (72) operable by a handle (64, 66) that when closed snugly fits around the biopsy needle probe (37) , thus being rigidly affixed by pressure clamping (Column 7, Lines 23-24 and Column 8, Lines 31-40; Fig. 10).

68. Concerning **claim 70**, Zurinski et al. disclose the template is capable of gripping the orientation probe (37) between two separable parts (4,6) of the gripping aperture,

and is further operable to release the probe when a squeezing pressure is applied to a handle (64, 66) of the template (Column 7, Lines 23-24 and Column 8, Lines 31-40; Fig. 10).

69. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schatzberger (WO 2004/002319) as applied to claim 38, in view of Kelly et al. (5,483,961, previously cited) and Migdal (*MRI Guided Hepatic Cryotherapy Using the CRYO-HIT™ System*, previously cited).

70. Concerning claim 41, Schatzberger fails to disclose the orientation probe being a solid probe devoid of differential parts. However, Kelly et al. disclose using a stylus (25) and displaying the position of the tip of the stylus using CT or MRI images to orient a surgeon with direct real-time comparison of the position of the stylus (25) tip in the surgical field with respect to the patient's anatomy (Column 8, Lines 66-67 and Column 9, Lines 1-4). As illustrated in Fig. 2 and Fig. 8, stylus (25) is a **solid probe devoid of differentiated internal parts** in the distal end that is inserted into the patient. Furthermore, it is known in the art to place an MR compatible 18G needle into the treatment target, where this needle is used as a reference positioning means, and then place a treatment needle such as a cryoprobe based on the confirmed position of the reference needle as exemplified in the teachings of Migdal (page 2) At the time of the invention, it would have been obvious to one of ordinary skill in the art to use a solid positioning needle which is devoid of differentiated internal parts as the orientation probe because as noted above: a) a solid probe devoid of differentiated internal parts is

an art recognized effective reference positioning means; b) it is also known to sequentially insert a reference positioning probe and a treatment probe to a target tissue. A preference on whether to use a catheter probe as suggested by Schatzberger or simply a solid probe devoid of differentiated internal parts is taken to be well within the purview of design choice in the art.

Allowable Subject Matter

71. Claims 10 and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

72. Applicant's arguments filed 9/10/2009 with respect to claims 1-46, 49-52, 53-63, 66-69 have been considered but are moot in view of the new ground(s) of rejection.

73. Applicant's arguments filed 9/10/2009 with respect to claims 37, 47-49, 53-58, 63, and 69-70 under the rejection of 102(b) by West (D260,727) have been fully considered and are persuasive. The rejection of claims 37, 47-49, 53-58, 63, and 69-70 and the rejection under 102(b) by West (D260,727) has been withdrawn. In respect to applicant's argument that no two holes of West's design are of the same size and thus would not be useable with any existing sets of multiple cryoprobes, the Examiner agrees. The Examiner notes, that it would have been an obvious matter of design choice to size the holes appropriately so the template is capable of rigidly affixing to the

size of the orientation probe and guiding the therapeutic probes, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955). However, Applicant's amended claim positively reciting an orientation probe overcomes this rejection.

74. Applicant's arguments filed 9/10/2009, with respect to the rejection(s) of claim(s) 37, 47-49, 53-58, 63, and 69-70 under the rejection of 102(b) by Zurinski et al. (4,542,747) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made under the rejection of 103(a) by Zurinski et al. In response to applicant's arguments that Zurinski's guide channels are all sized the same, and thus it would not be capable of rigidly affixing one probe while only constraining movement of another probe of equal diameter, the Examiner agrees. In response to applicant's arguments that the apparatus might be designed in which the size or shape of the therapeutic probes is accurately designed to be very slightly different from that of the orientation probe to be used with Zurinski's guide channels, and there is no such contemplated use mentioned or suggested by Zurinski, the Examiner disagrees. As discussed above, it would have been an obvious matter of design choice to size the probe guide channels not being used by the orientation probe or use smaller diameter therapeutic biopsy probes such that when a therapeutic probe is inserted, it can move through the guide channel and be constrained to move towards the treatment target, since such a modification would have involved a mere change in the size of a component. A change

in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955). Further, at the time of the invention, it would have been obvious to use variable diameter therapeutic biopsy needle probes in order to provide the benefit of taking differently sized biopsy samples. Thus, per these size changes in either the probe diameter or the guide channels which is within bounds of one of ordinary skill in the art as explained, Zurinski's device would be capable of both rigidly affixing to one probe while only constraining movement of another probe.

Conclusion

75. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAYMI DELLA whose telephone number is (571)270-1429. The examiner can normally be reached on M-Th 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571)272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Linda C Dvorak/
Supervisory Patent Examiner, Art Unit 3739

/J. D./
Examiner, Art Unit 3739
December 2, 2009